FDA & YOU
News for Health Educators and Students
Issue Number 1 **Fall 2003**

Toxic Shock Syndrome Is So Rare You May Forget It Can Happen

Toxic Shock Syndrome (TSS) is a rare but serious and sometimes fatal illness that is associated with using tampons. FDA recommends that women use tampons wisely and know the symptoms of TSS.

You can reduce your chance of getting TSS by:

- using the lowest absorbency tampon for your flow
- not extending wear time by using higher-absorbency tampons
- alternating tampons and pads to avoid the continuous use of tampons
- not using tampons

Remember to:

- change your tampon at least every 4 to 8 hours
- not use tampons between periods
- remove your last tampon at the end of your period

TSS is caused by bacteria called *Staphylococcus aureus*. These bacteria commonly exist on the skin and can also be found in the nose and vagina. Most of the time *S. aureus* is present in the body without problems, but it can cause infection. Some cases of TSS occur when the *S. aureus* bacteria produce poisons that pass into the bloodstream.

Women of all ages can get TSS. However, teenage girls and women under 30 are at a higher risk for TSS because they may not have developed antibodies to the bacteria poisons.

Know the Warning Signs of TSS:

- sudden fever (usually 102°F or higher),
- vomiting,
- diarrhea,
- dizziness,
- fainting or near fainting when standing up, or
- a rash that looks like a sunburn

TSS in History

In 1980 people realized just how serious TSS can be. That year 890 cases of the newly recognized illness were reported to the Centers for Disease Control and Prevention (CDC). A follow-up report from CDC described three studies linking TSS and the use of tampons. In 1982 FDA began requiring manufacturers to print package labeling advising women to use the lowest absorbency tampon necessary.

If You Experience Symptoms of TSS:

- contact your doctor immediately.
- if you are a teen without access to a doctor tell a parent or other trusted adult about your symptoms
- If you are wearing a tampon, remove it at once.

You should consult your doctor before using tampons if you have had any of the TSS warning signs in the past, or if you have any questions about TSS or tampon use.

To learn more about TSS, visit http://www.fda.gov/fdac/features/2000/200_tss.html.

A Note from FDA: *Welcome to the first issue of a new series, FDA & You. In this issue you will find valuable health and medical device information from FDA's Center for Devices and Radiological Health (CDRH) that we hope will encourage discussion and learning. You can read us online at http://www.fda.gov/cdrh/fdaandyou/ and check out some of CDRH's consumer websites at http://www.fda.gov/cdrh/consumer. Enjoy!*

Decorative Contact Lenses Could Cost You Your Sight

Excited about the approaching holiday season? Don't let reckless eye care ruin your special occasion.

FDA is warning consumers not to use decorative contact lenses obtained without a prescription or without proper fitting by a qualified eye care professional (i.e. doctor of optometry, ophthalmologist).

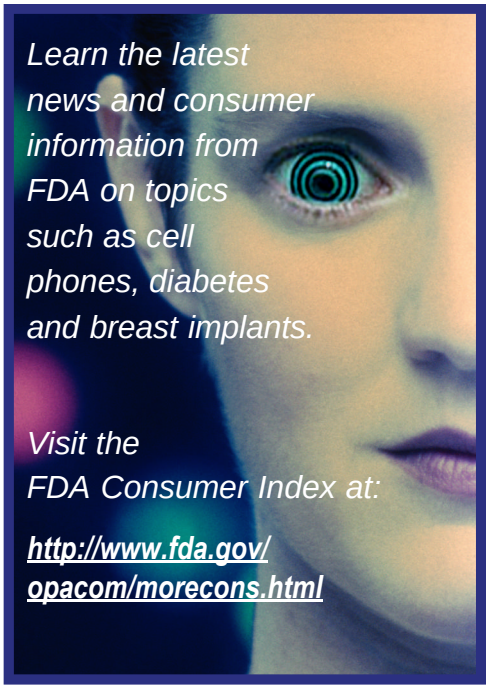
Decorative lenses have special effect printing or hand painting on the lens surface to change eye color or make human eyes resemble those of a cat, vampire, reptile, or have small designs such as smiley faces or sports team insignia.

These products are being marketed and distributed directly to consumers through flea markets, convenience stores, and beach shops. There is no guarantee that the lenses are sanitary or that the materials and colored pigments used to make them are safe.

FDA has issued an import alert instructing FDA personnel and officials of the U.S. Customs Service to automatically detain all decorative contact lenses presented at U.S. ports of entry. FDA will also seize decorative contact lenses currently on the market in violation of Federal law.

Non-corrective lenses of questionable manufacturing and worn without proper fitting pose significant risks to consumers including:

- allergic reactions,
- impaired vision,
- conjunctivitis and other infections,
- scarring of the cornea,
- blindness, or
- eye loss.



Contact Lens Tips

- Never wear contact lenses that have not been prescribed and fitted for your eyes by an eye care professional.
- Do not buy contact lenses from gas stations, video stores, or any vendor not authorized by law to sell contact lenses.
- Never swim while wearing contact lenses. There is a risk of eye infection when the lenses come into contact with bacteria in swimming pool water.
- Make sure to properly clean and disinfect contact lenses as instructed by your eye care professional.
- Wash your hands before handling and cleaning your contact lenses.
- Do not swap or share contact lenses with anyone.
- Never sleep while wearing contact lenses unless they are extended-wear lenses specifically designed for that purpose.

Yorick Goes to Washington!

Yorick, CDRH's bionic skeleton has moved to the Smithsonian Institution in Washington, D.C. The plastic skeleton, and the many medical devices he wears, will be on display November 14th and 15th at the National Museum of American History as part of a special program called "Inventing Ourselves." The September issue of *Smithsonian* magazine highlights Yorick's creation by former FDA engineer Ed Mueller in the 1970s and the skeleton's retirement from educational work.

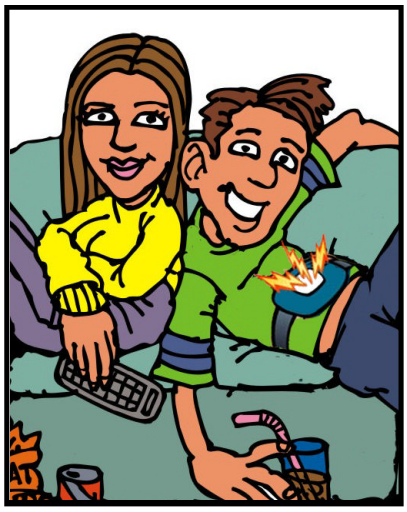
Visit Yorick on the web: http://www.fda.gov/oc/opacom/kids/html/yorick_no.1.htm
Read the article: http://www.smithsonianmag.si.edu/smithsonian/issues03/sep03/mall.html

Abdominal Muscle Stimulators: What Price Perfection?

In an image conscious culture, watching 30 minutes of sculpted abs swathed in spandex can make even the most reluctant consumer a soft sell. Over the past few years, the siren song of abdominal muscle stimulators has flooded the infomercial circuit and caught the attention of both the public and two Federal agencies.

The Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) are concerned about manufacturer claims that abdominal muscle stimulators can produce "six pack" abs and replace regular exercise and sensible eating habits. FDA's Center for Devices and Radiological Health (CDRH) has received reports that the use of these types of products causes injury and interference with medical devices.

An abdominal muscle stimulator is a battery-powered device (often in belt form) worn around the waist. When in use, the device delivers weak electrical current through electrodes attached to the body and causes the contraction of muscles underneath it. This type of energy transfer is known as electrical muscle stimulation (EMS).



Products using EMS are classified by FDA as medical devices and must meet regulatory standards before they can be sold. Over the past two decades, electrical muscle stimulators have been reviewed and cleared by FDA for use by healthcare professionals in rehabilitation and the treatment of certain medical conditions. FDA has also cleared some EMS products with limited claims for over-the-counter sale. However, in recent years, many manufacturers of abdominal muscle stimulators have not followed the FDA requirements for review and their devices have been sold illegally.

If a device does not comply with Federal review requirements, FDA will not know if the amount of electrical energy delivered by the device is safe. A poorly designed device can cause injury including burns, skin irritation and electrical shock. In addition, FDA is concerned that electrical interference from these stimulators can cause a malfunction of medical products, including pacemakers and insulin pumps.

According to reports received by FDA, many of the mass-marketed abdominal muscle stimulators do not meet advertising claims. Based on similar reports, the FTC is seeking permanent restrictions against manufacturers to prevent them from using further false or misleading advertising and requiring them to compensate defrauded customers.

For more information about abdominal muscle stimulators, visit the FDA consumer FAQ at http://www.fda.gov/cdrh/consumer/ems.html. For consumer tips from the FTC, visit http://www.ftc.gov/opa/2002/05/projectabsurd.htm.

Q. *Where can you report problems with medical products?*

Food and Drug Administration
MEDWATCH

A. *http://www.fda.gov/medwatch*

Digital Wireless Phones to be Compatible with Hearing Aids

On July 10, 2003, the Federal Communications Commission (FCC) modified the exemption for wireless phones under the Hearing Aid Compatibility Act of 1988. This means that wireless phone manufacturers and service providers must make digital wireless phones accessible to individuals who use hearing aids.

For more information visit http://www.fda.gov/cellphones.

Membership = Knowledge Join the ContactsListing Database

The Center for Devices and Radiological Health (CDRH) has information that it would like to share with people interested in medical devices and radiation-emitting products. We would like you to consider registering (it's FREE) in our ContactsListing Database.

When you register, you may choose areas of interest, geographic region, specialties, and affiliations that best describe you and your organization. CDRH will notify you by e-mail about issues that are related to your areas of interest such as:

- new issues of *FDA & You* posted on the CDRH web;
- upcoming teleconferences with viewing locations;
- recalls and safety issues;
- new websites;
- statements of policy or guidance posted on CDRH websites (e.g., *Federal Register* notices, press releases, and safety alerts)
- notifications of various activities such as public meetings; and
- invitations to collaborate with CDRH on research of a particular issue.

We invite consumers, health professionals, device user facilities, academia, device manufacturers, and other interested persons to join by registering at:

http://www.fda.gov/cdrh/contactslisting

Word Jumble

A	F	C	D	Q	Q	P	Z	L	M	N	N	A	S	C
S	O	D	X	E	V	P	L	A	C	I	D	E	M	O
O	S	T	A	N	D	A	R	D	S	R	N	P	E	N
R	Z	T	O	P	E	N	E	R	A	C	E	Y	E	T
C	O	N	S	U	M	E	R	P	F	M	P	H	S	A
S	D	I	A	G	N	I	R	A	E	H	A	H	I	C
E	C	I	V	E	D	R	C	H	T	L	A	E	H	T
X	N	O	P	M	A	T	A	I	Y	A	N	N	B	S
L	O	N	B	R	K	O	E	N	S	R	S	H	K	E

1. FDA
2. TSS
3. Tampon
4. Hearing aids
5. Device
6. Consumer
7. EMS
8. Medical
9. Standards
10. Health
11. Contacts
12. Safety
13. Eye care

About *FDA & You*

***FDA & You* is an FDA publication to inform and encourage health educators and students to learn about the latest FDA medical device and health news.**

The publication's contents may be freely reproduced. Comments should be sent to the Editor.

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